REMARKS

Claims 10, 12 and 17 are all the claims pending in the application.

Claim 10 is amended herein to further clarify the claimed invention. Support Is found, for example, at the paragraph bridging pages 29-30 of the specification as originally filed as discussed below. No new matter is presented.

Applicants note that a Petition to Withdraw Finality was previously filed on October 22, 2009. No Decision has yet been received on the Petition. Thus, Applicants repeat the Request to Withdraw Finality of the Office Action dated August 25, 2009 herein.

Applicants further traverse the rejection under 35 U.S.C. § 112, 1st paragraph, for new matter and the rejections under 35 U.S.C. § 103 for the reasons of record repeated herein.

I. Request to Withdraw Finality of the Office Action dated August 25, 2009

Applicant submits that the final Office Action dated August 25, 2009, improperly has been made final and thus respectfully solicits withdrawal of the finality of the Office Action.

Specifically, claims 10, 12 and 17 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that claims 10, 12 and 17 are drawn to pharmaceutical composition of solifenacin or a salt thereof for use in a solid formulation, the composition containing crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof, together with an inhibitor of an amorphous preparation, wherein the inhibitor of an amorphous preparation is a substance having an ethylene oxide chain and wherein the crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof is not in contact with or in mixture with the inhibitor of an amorphous preparation, which has no antecedent basis in the specification.

However, the Examiner did not specifically indicate why the passage from the specification provided in the Response filed June 16, 2009, is not sufficient to provide support for amended claim 10. For at least this reason, the Action is improper. MPEP § 707.07(f) requires the Examiner to provide clear explanations of all actions taken during the prosecution of the application in order to provide a complete prosecution history and to enhance clarity of the prosecution history record. Further, the Examiner should respond specifically to traversals. ("Where the applicant traverses any rejection, the examiner, should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.").

Additionally, it is improper to make the first Action after a RCE final where the Examiner previously refused to enter proposed claim amendments based on the assertion that the proposed amendment presented new matter. See MPEP § 706.07(b). In view of the Examiner's position, applicants filed an RCE and amended the claim language. Although the language in the present claims is slightly different from that in the Amendment filed April 16, 2009, which was not entered by the Examiner allegedly because the proposed amendment raised issues of new matter, the language is similar and the issue is the same.

Moreover, the Examiner states that "***if*** the new matter is removed from claim 10 the following rejections will be maintained:

(1) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Slatter et al., US 2004/0138253;

(2) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Fraser et al., US 2004/0198822;

(3) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Saito et al., US 2005/0181031; and

(4) the rejection of claims 10, 12 and 17 under 35 U.S.C. §102(e) over Fraser et al., US 2005/0239890.

This is also improper because the Examiner fails to address the claims as amended. MPEP §2163.06(I) clearly states that even when a new matter rejection is made, the Examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by Applicant.

For the reasons discussed above, Applicant requests that the finality of the Office Action be withdrawn and a new Non-Final Office Action with a new time period for reply should be issued addressing the claims as amended and providing a clear explanation as to why the disclosure in the specification is not considered sufficient to provide support for amended claim 10.

II. Response to Rejection under 35 U.S.C. § 112, 1st paragraph

Claims 10, 12 and 17 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner states that claims 10, 12 and 17 are drawn to pharmaceutical composition of solifenacin or a salt thereof for use in a solid formulation, the composition containing crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof, together with an inhibitor of an amorphous preparation, wherein the inhibitor of an amorphous preparation is a substance having an ethylene oxide chain and wherein the crystalline and amorphous solifenacin or a crystalline and amorphous salt

thereof is not in contact with or in mixture with the inhibitor of an amorphous preparation, which has no antecedent basis in the specification.

Applicants consider that the Examiner is referring specifically to the recitation of "and wherein the crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof is not in contact with or in mixture with the inhibitor of an amorphous preparation", which was added in the Amendment filed June 16, 2009, as not having antecedent basis in the specification. However, the Examiner did not specifically indicate why the passage from the specification provided in the Response filed June 16, 2009, is not sufficient to provide support for amended claim 10.

Claim 10 was amended to recite that the solifenacin is "not in contact with or in mixture with the inhibitor of amorphous preparation" to further clarify the claimed invention. The amendment to claim 10 is supported by the disclosure at the paragraph bridging pages 29-30 of the specification as filed, which corresponds to paragraph [0065] of the published application, Pub. No. 2008/0039516. The disclosure states:

> In accordance with the invention, the phrase "containing" means that solifenacin or a salt thereof as the active pharmaceutical ingredient is in mixture with the inhibitor of amorphous preparation. Preferably, solifenacin or a salt thereof is in contact with an inhibitor of amorphous preparation so that solifenacin or a salt thereof is distributed in a state of mixture. *As in the case of using a pharmaceutical composition as a coating agent of solifenacin formulation wherein the active pharmaceutical ingredient, solifenacin or a salt thereof,* ***is not in contact with or in mixture with such inhibitor of amorphous preparation*** so that it exists in a localized state (for example the inhibitor of amorphous preparation in accordance with the invention (PEG)), pharmaceutical preparations for example at a state *such that* ***solifenacin or a salt thereof is not in physical contact with a***

> ***inhibitor of amorphous preparation*** *in an intermediate layer using other additives and the like are excluded* (emphasis added).

This disclosure clearly refers to an embodiment wherein crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof is mixed with, or in contact with, an inhibitor of an amorphous preparation and also excludes an embodiment wherein the solifenacin or salt thereof is coated with a coating agent and the inhibitor of an amorphous preparation is contained in the coating layer and is not mixed with or in contact with, the solifenacin or salt thereof, which is contained in another layer. Thus, the amendment to claim 10 as in the Amendment filed June 16, 2009 (and the Amendment previously filed on April 16, 2009), is supported by the specification as filed and is not new matter.

Claim 10 is further amended herein based on the disclosure above to clarify that an embodiment wherein the solifenacin or salt thereof is coated with a coating agent and the inhibitor of an amorphous preparation is contained in the coating layer and is not mixed with or in contact with, the solifenacin or salt thereof, which is contained in another layer, is excluded from the scope of the present claims. Such language is permitted as explained in MPEP § 2173.05(i) which states that negative limitations and exclusionary provisos are permitted in the claims if there is basis in the original disclosure (see MPEP § 2173.05(i)). Specifically, if alternative elements are positively recited in the specification they may be explicitly excluded in the claims.

Accordingly, Applicants respectfully request withdrawal of the new matter rejection under 35 U.S.C. § 112, 1st paragraph.

III. Response to Prior Art Rejections

Claims 10, 12 and 17 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Slatter et al., US 2004/0138253.

Claims 10, 12 and 17 are rejected under 35 U.S.C.§ 102(e) as allegedly being anticipated by Fraser et al., US 2004/0198822.

Claims 10, 12 and 17 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Saito et al., US 2005/0181031.

Claims 10, 12 and 17 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Fraser et al., US 2005/0239890.

Applicants respectfully traverse for the reasons of record as follows.

Slatter et al

As previously noted, Slatter et al does not disclose, teach or suggest the existence of amorphous solifenacin or a composition of solifenacin or a salt thereof for use in a solid formulation. Thus, for at least this reason, Slatter et al does not anticipate the present invention.

Further, although Slatter et al describes various compounds as anti-muscarinic agents, Slatter et al does not disclose, teach or suggest a specific embodiment of a pharmaceutical composition of solifenacin and a salt thereof containing crystalline and amorphous solifenacin or a crystalline and amorphous salt thereof, together with an inhibitor of an amorphous preparation which is a substance having an ethylene oxide side chain as required in claim 10. For this additional reason, the present invention is not anticipated by Slatter et al.

Moreover, Slatter et al does not disclose, teach or suggest a substance having an ethylene oxide chain, as an inhibitor of an amorphous preparation as recited in present claim 10. For example, Slatter et al describes:

> The carriers may be any inert material, organic or inorganic, suitable, for administration, such as: water, gelatin, gum arabicum, lactose, microcrystalline cellulose, starch, sodium starch glycolate, calcium hydrogen phosphate, magnesium stearate, talcum, colloidal silicon dioxide, and the like.

However, there is no description of a substance having an ethylene oxide chain.

Even further, the technical object of Slatter and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Slatter et al with a reasonable expectation of success. Even assuming that a composition could be prepared by preparing a compound for aerosol administration using solifenacin, as in Slatter et al, there is no description about a concrete means for solving the problem. For these additional reasons, the present invention is patentable over Slatter.

Fraser et al '822 and Fraser et al '890

As previously noted, Fraser et al '822 and Fraser et al '890 do not disclose, teach or suggest the existence of amorphous solifenacin or a composition of solifenacin or a salt thereof for use in a solid formulation Thus, for at least this reason, Fraser et al does not anticipate the present invention. Further, the Fraser et al references do not disclose teach or suggest a mixture of solifenacin or a salt thereof as an active ingredient together, i.e., mixed, with an inhibitor of an amorphous preparation as recited in present claim 10. For this additional reason the present invention is not anticipated by the Fraser et al references.

The Fraser et al references disclose a method for using an $\alpha_2\delta$ subunit calcium channel modulator and a compound having smooth muscle modulatory effects to increase effectiveness and lower the side effects. Solifenacin, which is a antimuscarinic agent, is disclosed as a smooth muscle modulating factor. The Fraser et al references describe many factors for controlling the smooth muscle and solifenacin is merely one of many drugs. However, one would have to pick and choose amongst the many drugs mentioned and such "picking and choosing" is inappropriate for an anticipation rejection. Additionally, there is no apparent reason to specifically select solifenacin.

Even further, one of ordinary skill in the art would not have been motivated to modify the disclosure of the Fraser et al references with a reasonable expectation of success in achieving the presently claimed invention.

For one reason, the technical object of Fraser et al and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. The Fraser et al references ('822 at paragraph [295] and '890 at paragraph [294]) describe tablets etc., as the oral administration forms. At paragraph [297] of the '822 reference provided below (and paragraph [296] of the '890 not provided below) reference polyethylene glycol etc., is described as the binder. Moreover, it is described that the binder is used to impart adhesiveness to the compression molded tablet. In other words, as the oral administration form, the drug exists within the tablet and the binder such as polyethylene glycol is placed to surround the tablet, so that it is considered that the tablet and the binder exist without mixing with each other in the Fraser et al references.

> **[0297]** In addition to the active agent(s), then, tablets prepared for oral administration using the method of the invention will generally contain other materials such as binders, diluents, lubricants, disintegrants, fillers, stabilizers, surfactants, preservatives, coloring agents, flavoring agents and the like. Binders are used to impart cohesive qualities to a tablet, and thus ensure that the tablet remains intact after compression. Suitable binder materials include, but are not limited to, starch (including corn starch and pregelatinized starch), gelatin, sugars (including sucrose, glucose, dextrose and lactose), polyethylene glycol, propylene glycol, waxes, and natural and synthetic gums, e.g., acacia sodium alginate, polyvinylpyrrolidone, cellulosic polymers (including hydroxypropyl cellulose, bydroxypropyl methylcellulose, methyl cellulose, ethyl cellulose, hydroxyethyl cellulose, and the like), and Veegum.

On the other hand, the present specification provides:

> Preferably, solifenacin or a salt thereof is in contact with an inhibitor of amorphous preparation so that solifenacin or a salt thereof is distributed in a state of mixture. As in the case of using a pharmaceutical composition as a coating agent of solifenacin formulation wherein the active pharmaceutical ingredient, solifenacin or a salt thereof, is not in contact with or in mixture with such inhibitor of amorphous preparation so that it exists in a localized state (for example the inhibitor of amorphous preparation in accordance with the invention (PEG)), pharmaceutical preparations for example at a state such that solifenacin or a salt thereof is not in physical contact with a inhibitor of amorphous Preparation in an intermediate layer using other additives and the like are excluded.

From this description, it is apparent that the means for solution is different between the present invention and the Fraser et al references. Even assuming that solifenacin could be selected among the drugs described in the references, the position of the inhibitor of solifenacin preparation is different and there is no motivation to position the inhibitor to be mixed with the drug as in the present invention. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Fraser et al with a reasonable expectation of success of achieving

the presently claimed invention. For this additional reason, the present invention is patentable over the Fraser et al references.

Saito et al

As previously pointed out, Saito et al neither discloses, teaches nor suggests the existence of amorphous solifenacin. Thus, for at least this reason, Saito et al does not anticipate the present invention. Additionally, Saito does not disclose, teach or suggest the presently claimed invention as recited in amended claim 10.

Saito et al describes a transdermal preparation comprising a substance having an ethylene oxide chain as an optional pharmaceutically acceptable excipient ([0033]) among many excipients. However, one would have to pick and choose among the many excipients to arrive at a substance having an ethylene oxide chain among many excipients and such "picking and choosing" is inappropriate in an anticipation rejection.

Even further, the technical object of Saito et al and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Saito et al with a reasonable expectation of success. For this additional reason, the present invention is patentable over Saito et al.

In summary, none of the references teaches or suggests all elements of the presently claimed invention. Accordingly, the invention of amended claim 10 is both novel and non-obvious. Claims 12 and 17 depend directly, or indirectly from claim 10 and are patentable for at least the same reasons.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102.

IV. Response to Obviousness-Type Double Patenting Rejection

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-13 of Umejima et al., US 2008/0103171.

Without conceding the merits of the rejection, Applicants respectfully defer responding to the rejection and request that the rejection be held in abeyance.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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